

To: Elizabeth Campbell
Senior Counsel
AmerisourceBergen Corporation

Date: July 27, 2014

Fm: Michael Mapes
CSRA DEA Consultant

Cc: Chris Zimmerman
Steve Mays
David May
Ed Hazewski

Re: ABC Order Monitoring Program Review
June 12, 2014

Attorney/Client Privileged Communication

PURPOSE OF REVIEW:

From June 11, 2014, to June 12, 2014, Michael Mapes, CSRA Consultant, reviewed the Order Monitoring Program (OMP) at AmerisourceBergen Drug Company in Chesterbrook, PA. The review included a review CSRA policies and procedures, the CSRA 590 process, the process for orders that have been held by the OMP system, a review of the current threshold levels for the various customers, and a review of the Chain Pharmacy initiative by CSRA.

Information for the review was obtained from reviews of documents and discussions with Ed Hazewski, the Director of the Diversion Control Program for ABC, Liz Garcia, Kevin Kreutzer, Eric Martin, and Kimberly St. John.

A significant amount of time during the review was spent discussing the FTI Consulting project to update the ABC diversion control program.

BACKGROUND:

The OMP program at ABC is constantly changing to address the changes to the drug diversion situation and changes to ordering patterns by ABC customers. The ABC OMP is well managed and appears to be very effective at mitigating the risk associated with the distribution of controlled substances by ABC. The following are issues that were identified during the August 2013 review related to the OMP:

1. For chain store customers, review information at the chain store corporate level to ensure that the chain corporation has policies and procedures in place to mitigate the risk of the diversion of controlled substances and listed chemicals. The corporate review should include:

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2. The issue of contacting the local DEA office for each Customer Due Diligence (CDD) investigation may be having negative consequences on the relationship between ABC and DEA. DEA personnel are generally prohibited from providing information on on going investigations, so asking DEA to provide the information can be interpreted as asking DEA to violate their policies.
3. When CSRA completes a Prescribers Big Report (PBR), prescribers that raise the level of concerns for the prescriptions filled at a specific pharmacy are identified. CSRA usually advises the pharmacy that there is a concern with the prescriptions from specific doctors and advises that ABC is reducing the threshold levels for specific products. The specific prescriber with the suspect prescriptions is also placed on the Suspicious Prescriber List (SPL). Currently, the SPL is not reviewed to determine if the prescribers who have been identified as suspicious at one pharmacy have been identified by another pharmacy as prescribers for which the second pharmacy fills prescriptions. The SPL should be checked whenever a 590 or threshold increase results in the identification of specific prescribers.
4. When a PBR is initiated, CSRA should consider initiating a Google Alert for the pharmacy or prescribers that are the subject of the PBR. The Google Alert will monitor the Internet and news releases related to the pharmacy or prescriber.
5. CSRA should draft a policy for when PBR reports are initiated, and for what is contained in a PBR report. Will all PBR's contain 90 days of data and what analysis will be completed?
6. CSRA Policy Number 3.4, requires that on an annual basis the RVP's will review and certify that their accounts continue to remain in compliance with the intent and spirit of policy 3.4. No certifications of the compliance by the RVP's were located at CSRA.
7. When completing documentation of investigations in Law Trac, ensure that the documentation is complete and consistent. Some investigators are checking all employees of a pharmacy in Google and with the state board, but only making a general comment in Law Trac that state board and Internet checks have been made. Additionally, some comments in the SAP order monitoring system reported orders being "Rejected as Compliant."
8. During the CSRA 590 process, some pharmacies advise that they have not received a Self-Certification for Listed Chemicals. Further investigation should be undertaken to determine if the pharmacy intends to obtain a Self-Certification, if they did not understand the question or if they are not going to handle Listed Chemicals such as pseudoephedrine products. If the pharmacy does not have a Self-Certification, ABC should not sell Listed Chemicals to the pharmacy.

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Each of the issues recommendations from the 2013 review was addressed by ABC, as described in a memorandum, dated November 1, 2013 from Edward Hazewski.

The implementation of the ABC OMP into the Walgreen's process for their stores was discussed. It appears that the OMP is working well with the Walgreens stores, partly due to the internal Walgreen's policies and procedures that are in place to prevent suspicious orders and the communication between CSRA and Walgreens.

The main issue that was identified during the audit was the differences in the OMP between ABC, Belco, and ABC Specialty companies. This issue is being addressed with reviews at the other companies to ensure that all of the ABC companies have consistent policies and procedures in place and that each organization is following the policies and procedures.

The review of documents and discussions with the CSRA personnel did not identify any other issues of concern.

Should you have questions concerning this matter, please contact me at mrmapes@gmail.com or 719-650-0294.

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